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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,301	03/09/2003	Frank M Fago	1628 WO/US	2534

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EXAMINER
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BUI, LUAN KIM

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/527,301

Applicant(s)

FAGO ET AL.

Examiner

Luan K. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-7,10,11,13-19 and 22-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3,5-7,10,11,13-19 and 22-26 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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After further reconsideration of the previous Office Action mailed on 8/30/2005, the Examiner is hereby withdrawn the previous Office Action in favor of the instant Office Action.

*Specification*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

2. The specification is objected to under 37 CFR 1.71, as the specification, as originally filed, does not provide support for the new matter as now claimed. The specification as filed does not provide support for the phrase "molded about an entirety" in the amendments filed on 3/9/2003 in claim 22, because the specification only discloses "completely encloses". The phrase "completely encloses" is clearly different from the phrase "molded about an entirety".

3. Claims 22-26 are rejected under 35 USC 112, first paragraph, for the reasons set forth in

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the objection to the specification.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 2, 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanke et al. (20030141210; hereinafter Yanke'210) in view of Kronberg (5,334,847). Yanke'210 discloses a pharmaceutical pig (10) for holding a syringe containing radiopharmaceutical liquid comprising a base (14) including a base shielding element made of a radiation blocking material (22) disposed within a base shell (18) made of a polymer material and a cap (26) removably attached to the base. The cap comprises a cap shielding element (34) made of a radiation blocking material disposed within a cap shell (30) made of a polymer material. The base defined a first hollow center section to receive the body portion of the syringe and the cap defined a second hollow center section to receive the plunger portion of the syringe (Figures 1-4).

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Yanke'210 also discloses the other claimed limitations except for the base shell being completely enclosed the base shielding element and the cap shell being completely enclosed the cap shielding element.

Kronberg shows a container (10) comprising a base (14) having a cavity (16) for receiving radioactive material and the base including a base shell (32) completely encloses a base shielding element (18) made from a radiation blocking material and a cover (12) including a cover shell (34) completely encloses a cover shielding element (18) made from a radiation blocking material. It would have been obvious to one having ordinary skill in the art in view of Kronberg to modify the pig of Yanke'210 so the base shell is completely enclosed the base shielding element and the cap shell is completely enclosed the cap shielding element for better protecting the contents within the pig such as to prevent leakage through the pig.

As to claims 2, Yanke'210 discloses the threads (86, 144).

As to claim 6, see claims 11 and 18 of Yanke'210.

As to claim 17, Yanke'210 discloses an O-ring (38)/a fluid-tight seal located between the cap and the base.

7. Claims 7, 19, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 6 above, and further in view of Reich (5,672,883). Yanke'210 further fails to show the plastic material comprises polycarbonate resin. Reich shows a pharmaceutical pig comprising a base and a cap are made of plastic material and the plastic material includes polycarbonate resin. It would have been obvious to one having ordinary skill

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in the art in view of Reich to modify the pharmaceutical pig of Yanke'210 as modified so the plastic material comprises polycarbonate resin for better protecting radiation.

As to claim 19, Yanke'210 discloses a protrusion disposed between the base shell near an open end (Figure 13).

As to claim 19, Yanke'210 discloses a protrusion (near 132, 182) disposed near an open end of the base shielding element and adjacent to a shoulder portion of the base shielding element.

As to claim 22, Yanke'210 discloses the first hollow center section in the base configured to receive a syringe which includes a barrel, finger grips and a plunger. To the extent that Yanke'210 fails to show the first hollow center section configured to accommodate the syringe includes a needle, it would have been obvious to one having ordinary skill in the art in view of Reich to modify the syringe of Yanke'210 so it includes a needle to provide the syringe ready to use and to provide more convenience for the user.

As to claim 23, Yanke'210 discloses the base shielding element and the cap shielding element include lead (page, paragraph 0026).

As to claim 26, Reich shows the finger grip (104) of the syringe contacts a shoulder of the base near an open end of the base (Figures 3 and 7).

8. Claims 10, 11, 13-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 22 above, and further in view of Fu et al. (6,576,918; hereinafter Fu'918). Yanke'210 further fails to show a bottom portion of the base being substantially bell-shaped with plurality of flattened portions and a bottom portion of the cap includes a plurality of flattened portions. Fu'918 discloses a pharmaceutical pig (10)

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comprising a base (18) including a bottom portion and the bottom portion is substantially bell-shaped with a plurality of channels (98) and a top portion having a plurality of flattened portions (87) and a cap having a bottom portion with a plurality of flattened portions (59). It would have been obvious to one having ordinary skill in the art in view of Fu'918 to modify the shape of the pharmaceutical pig of Yanke'210 so the bottom portion of the base is substantially bell-shaped with a plurality of channels or flattened portions and the bottom portion of the cap includes a plurality of flattened portions to facilitate gripping the pig during opening and/or closing the pig and also the selection of the specific shape for the pharmaceutical pig would have been an obvious matter of design choice inasmuch as the resultant structures will work equally well and inasmuch as applicant's specification does not state that using these specific shapes as claimed solves any particular problem or yields any unexpected results.

As to claim 11, Yanke'210 discloses a top portion of the base (next to the threads 86) is substantially cylindrical.

As to claim 13, Fu'918 shows the base comprises a top portion (68) having a first diameter, a middle portion (66) having a second diameter, and a bottom portion (96, 100) having a third diameter.

As to claim 14, Yanke'210 further discloses the cap comprises a top portion (138) having a fourth diameter and a bottom portion (58) having a fifth diameter (Figure 10).

As to claims 15, 16 and 24, see the flattened portions (59, 87) of Fu'918.

9. Claims 3, 5, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 2 and 22 above, and further in view of Hutcheson (6,781,142).

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Yanke'210 further fails to show the thread being located on the cap and the base do not allow the cap to rotate more than ninety degrees in relation to the base and at least one locking detent associated with the threads. Hutcheson suggests a radiation-shielding container comprising at least one locking detent (56, 70, 106, 110, 112) associated with threads in a base (14) and a cap (18) and the threads do not allow the cap to rotate more than ninety degrees in relation to the base because of the two locking detents (106) (Figures 1-5). It would have been obvious to one having ordinary skill in the art in view of Hutcheson to modify the threads of Yanke'210 so it includes at least one locking detent for further securing the cap to the base and the threads do not allow the cap to rotate more than ninety degrees in relation to the base to facilitate closing and opening the container.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is 571-272-4552. The examiner can normally be reached on 8:30-6.

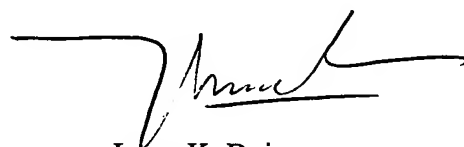
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. **The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for Formal papers and After Final communications.**



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lkb  
January 3, 2006



Luan K. Bui  
Primary Examiner  
Art Unit 3728